December 15, 2022

W. L. Gore & Associates, Incorporated
Barbara L. Smith, RAC
Official Correspondent
301 Airport Rd.
Elkton, Maryland 21921

Re: K132397
Trade/Device Name: Gore® Bio-A® Wound Matrix
Regulatory Class: Unclassified
Product Code: QSZ

Dear Barbara L. Smith, RAC:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 7, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSZ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

W.L. Gore & Associates Incorporated
% Ms. Barbara L. Smith, RAC
Regulatory Associate
301 Airport Road
Elkton, Maryland 21921

Re: K132397
Trade/Device Name: GORE® BIO-A® Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 2, 2014
Received: April 7, 2014

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.05.07 12:01:48 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132397

Device Name

GORE® BIO-A® Wound Matrix

Indications for Use *(Describe)*

The GORE® BIO-A® Wound Matrix is intended for use in the management of wounds.

Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Cynthia Chang

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
(Per 21CFR807.92)

Submission Information

Owner/Operator:
W. L. Gore & Associates, Inc.
1505 N. Fourth Street
Flagstaff, AZ 86004
USA

Regulatory Contact:
W. L. Gore & Associates, Inc.
301 Airport Road
Elkton, Maryland 21921
Attn: Barbara L. Smith, RAC
Phone: 410-506-8189
Fax: 410-506-8221
E-mail: blsmith@wlgore.com

Date Summary Prepared

April 29, 2014

Device Names/Classification

Trade Name: GORE® BIO-A® Wound Matrix

Common Name: Wound Dressing

Classification Name: Unclassified

Product Code: FRO (Dressing, wound, drug)

Predicate Device

The predicate devices to which the GORE® BIO-A® Wound Matrix is being compared are:

- K021792 INTEGRA™ Bilayer Matrix Wound Dressing (FRO)
- K022127 AVAGEN Wound Dressing (KGN)
- K090160 SUPRATHEL® Wound & Burn Dressing (FRO)
- K083266 GORE® BIO-A® Fistula Plug (FTL)

Intended/Indications for Use

The GORE® BIO-A® Wound Matrix is intended for use in the management of wounds.

Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds.

Device Description

GORE® BIO-A® Wound Matrix device is a tailorable, porous, bioabsorbable material matrix that provides a scaffold for cellular infiltration and vascularization. The device permits the ingress of cells and soft tissue formation into the defect space/wound bed. GORE® BIO-A® Wound Matrix is a porous fibrous structure composed solely of a synthetic copolymer comprised of polyglycolic acid and trimethylene carbonate (PGA:TMC).

Summary of Similarities and Difference in Technological Characteristics, Performance and Intended Use

The primary difference between the subject Wound Matrix device and Integra (Avagen) predicate is in the material type i.e. synthetic polymer scaffold vs. a collagen scaffold.

Performance Data / Predicate Device Comparison

Pre-Clinical

Bench study: Testing of the GORE® BIO-A® Wound Matrix device demonstrated the performance of the GORE® BIO-A® Wound Matrix is capable of meeting intended product specifications which are similar to the predicate Gore device comprised of the same material construct.

Animal study: Testing of the GORE® BIO-A® Wound Matrix device also included biocompatibility testing in accordance with ISO 10993-1 and in vivo safety and performance studies. The performance of the GORE® BIO-A® Wound Matrix device and the collagen predicate control device was evaluated in both full and partial thickness wounds in a porcine model analysis including wound closure, macroscopic appearance, and microscopic evaluation via histological assessment. The results of the studies showed that the test and predicate control device exhibited no adverse tissue response, a similar inflammatory response, and no differences in time to wound closure. All wounds healed prior to device absorption, and the devices were no longer histologically detectable at 8 months.

Clinical

No clinical evaluations of this product have been conducted.

Conclusion

W. L. Gore & Associates concludes the GORE® BIO-A® Wound Matrix is *substantially equivalent* to the predicate devices based upon similarities in product indications, operation, design, materials of construction, sterilization, labeling, shelf life, and performance.